



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2012-0842; FRL-9372-8]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 9 chemical substances which were the subject of premanufacture notices (PMNs). This action requires persons who intend to manufacture, import, or process any of these 9 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This rule is effective on *[insert date 60 days after date of publication in the Federal Register]*. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on *[insert date 14 days after date of publication in the Federal Register]*.

Written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs must be received on or before *[insert date 30 days after date of publication in the Federal Register]* (see Unit VI. of the **SUPPLEMENTARY INFORMATION**). If adverse comment is received, EPA will publish a timely withdrawal of the rule in the Federal Register.

For additional information on related reporting requirement dates, see Units I.A., VI., and VII. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2012-0842, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. ATTN: Docket ID Number EPA-HQ-OPPT-2012-0842. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2012-0842. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or email. The [regulations.gov](http://www.regulations.gov) website is an

“anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject

to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address:

moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Manufacturers, importers, or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at

19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule on or after [*insert date 30 days after date of publication in the **Federal Register***] are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA is promulgating these SNURs using direct final procedures. These SNURs will require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of a chemical substance for any activity designated by these SNURs as a significant new use. Receipt of such notices allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue

of April 24, 1990 (55 FR 17376) (April 24, 1990 SNUR). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. Persons who must report are described in § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6,

or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 9 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for 9 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the SNUR.
- Toxicity concerns.
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
- CFR citation assigned in the regulatory text section of this rule.

The regulatory text section of this rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits (i.e., limits on manufacture and importation volume) and other uses designated in this rule, may be claimed as CBI. Unit IX. discusses a procedure companies may use to ascertain whether a proposed use constitutes a significant new use.

This rule includes SNURs on 9 PMN substances that are not subject to consent orders under TSCA section 5(e). In these cases, for a variety of reasons, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use

scenario described in the PMN could result in increased exposures, thereby constituting a “significant new use.” These so-called “non-5(e) SNURs” are promulgated pursuant to § 721.170. EPA has determined that every activity designated as a “significant new use” in all non-5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, “(i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified” for the PMN substance.

PMN Number P-09-107

Chemical name: Fatty acids, tall-oil, reaction products with modified fatty acids and polyalkanolamines (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as an asphalt emulsifier. Based on test data on the PMN substance, and ecological structural activity relationships (EcoSAR) analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 110 parts per billion (ppb) of the PMN substance in surface waters. As described in the PMN, releases of the PMN substance are not expected to result in surface water concentrations that exceed 110 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface

water concentrations exceeding 110 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10629.

PMN Numbers P-11-619 and P-11-620

Chemical name: Amino acid, carboxyalkyl, alkylsulfonate, alkali salts (generic).

CAS number: Not available.

Basis for action: The consolidated PMN states that the generic (non-confidential) use of the substances will be as an industrial cleaning solution component. Based on test data on the PMN substances and EcoSAR analysis of test data on analogous polyanionic monomers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 770 ppb for the aggregate of the PMN substances in surface waters. As described in the PMN, releases to surface waters are not expected to exceed 770 ppb for the aggregate of the PMN substances. Therefore, EPA has not determined that the proposed manufacturing or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding 770 ppb for the aggregate of the PMN substances may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.

CFR citation: 40 CFR 721.10630.

PMN Number P-12-64

Chemical name: Mixed metal borate (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an illuminating phosphor. Based on test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung overload and oncogenicity to workers exposed to the PMN substance. At the production volume described in the PMN, and because the uses described in the PMN do not use an application method that generates a vapor, mist, aerosol, or dust significant worker exposure is minimal. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance exceeding the confidential annual manufacture and import volume stated in the PMN or any use of the substance using an application method that generates a vapor, mist, aerosol, or dust may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C) and (b)(3)(ii).

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Guidelines 870.3465) with a 60-day holding period; dry particle size distribution/counting by transmission electron microscope (TEM) or scanning electron

microscopy (SEM) methods; and images of the powder for morphology would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10631.

PMN Number P-12-181

Chemical name: Benzamide, N-[(cyclohexylamino)thioxomethyl]-.

CAS number: 4921-92-0.

Basis for action: The PMN states that the use of the substance is as a cure initiator in adhesive formulations. Based on analysis of test data on analogous thioureas, EPA identified concerns for thyroid toxicity, developmental toxicity, and developmental neurotoxicity to the general population exposed to the PMN substance. Based on EcoSAR analysis of test data on analogous imides and thioureas, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substance in surface waters. For the uses described in the PMN, significant general population exposure is unlikely, as use in consumer product is not expected and releases of the PMN substance are not expected to result in surface water concentrations that exceed 2 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance in consumer products or use of the substance resulting in surface water concentrations exceeding 2 ppb may cause serious health effects or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C), (b)(3)(ii), and (b)(4)(ii).

Recommended testing: EPA has determined that the results of an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); fish acute

toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); algal toxicity test (OCSPP Test Guideline 850.4500); and a combined repeated dose toxicity with the reproduction/developmental toxicity screening test (OPPTS Test Guideline 870.3650) would help characterize the environmental and health effects of the PMN substance.

CFR citation: 40 CFR 721.10632.

PMN Number P-12-276

Chemical name: Aromatic sulfonic acid amino azo dye salts (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic use of the PMN substance will be in exhaust dyeing of cellulosic fabrics. Based on the alkylation potential of the PMN substance, there are concerns for skin and lung sensitization; mutagenicity; oncogenicity; and developmental, liver, and kidney toxicities. In addition, there are concerns for mutagenicity and oncogenicity, based on the beta-aromatic azo reduction product, as this PMN substance is expected to undergo azo reduction in the GI tract with good absorption potential of the reduction products. As described in the PMN, EPA does not expect significant exposure to workers. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without the use of a NIOSH-certified M100 respirator with an APF of 10 or any increase in the annual manufacture and import volume of 10,000 kilograms (kgs) of the substance, could change the potential for exposure correspondingly, and may result in serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(c) and (b)(3)(ii).

Recommended testing: EPA has determined that results of an Ames test with the Prival modification (OPPTS Test Guideline 870.5100), and an unscheduled DNA synthesis test in mammalian cells in culture (OPPTS Test Guideline 870.5550) would help characterize the health effects of the PMN substance. The test material for the unscheduled DNA synthesis test must be the specific sulfonated beta-aromatic amine that would result from the azo reduction of the PMN substance, rather than the intact PMN compound. It is necessary that the specific sulfonated-aromatic amine in question be isolated prior to testing. For both tests, the beta-aromatic amine is to serve as an additional positive control.

CFR citation: 40 CFR 721.10633.

PMN Number P-12-464

Chemical name: Iodonium, diphenyl-, 4,4'-di-C10-13-alkyl derivs., (OC-6-11)-hexafluoroantimonates(1-)

CAS number: 1370442-66-2.

Basis for action: The PMN states that the substance will be used as a photoinitiator used for ultraviolet release coatings. Based on the EcoSAR analysis of test data on analogous cationic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 8 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the PMN substance to surface water exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 8 ppb for more than 20 days per year.

Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as described in the PMN could result in exposures which may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance. When testing the PMN substance, if difficulty is encountered in dissolving the chemical in the test media, the submitter may wish to consult the special considerations for conducting aquatic laboratory studies (OPPTS Test Guideline 850.1000).

CFR citation: 40 CFR 721.10634.

PMN Number P-12-480

Chemical name: Alkyl maleimide substituted bicyclic olefin (generic).

CAS number: Not available.

Basis for action: The PMN states that substance will be used as a monomer in the manufacture of a specialty polymer. Based on EcoSAR analysis of test data on analogous imides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the PMN substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk.

EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects.

Based on this information, the PMN substance meets the concern criteria at

§ 721.170(b)(4)(ii).

Recommended testing: EPA has determined that an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance. When testing the PMN substance, if difficulty is encountered in dissolving the chemical in the test media, the submitter may wish to consult the special considerations for conducting aquatic laboratory studies (OPPTS Test Guideline 850.1000).

CFR citation: 40 CFR 721.10635.

PMN Number P-12-501

Chemical name: Slimes and sludges, automotive coating, wastewater treatment, solid waste.

CAS number: 1392095-50-9.

Chemical substance definition: The waste solids produced from the treatment of wastewaters from automotive pretreatment processes, electro-deposition coating processes, surface coating processes and topcoat coating processes. It may contain oxides of iron, calcium, aluminum, zinc, nickel, and magnesium.

Basis for action: The PMN substance will be used as a feedstock replacement in cement kiln production. Based on analogous crystalline chemical substances, EPA identified

concerns for potential oncogenicity. These concerns are for effects to workers from inhalation exposure to the PMN substance in powder form. For the uses described in the PMN, significant worker exposure is unlikely, as inhalation exposure is not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that the manufacture, processing, or use of the substance in powder form may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(1)(i)(C).

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance. Test should be conducted with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and to various parameters of the bronchoalveolar lavage fluid (BALF), e.g., marker enzyme activities, total protein content, total cell count, cell differential, and cell viability. It is not necessary to look at internal organs. A recovery period of 60 days should be included to assess the progression or regression of any lesions. If the results of the 90-day inhalation toxicity test indicate that the PMN particles have carcinogenic potential, a 2-year inhalation bioassay in rats may be warranted.

CFR citation: 40 CFR 721.10636.

V. Rationale and Objectives of the Rule

A. Rationale

In these 9 cases, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit IV.

B. Objectives

EPA is issuing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

- EPA will receive notice of any person's intent to manufacture, import, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for the described significant new use.
- EPA will be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at

<http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

VI. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule, as described in § 721.160(c)(3) and § 721.170(d)(4). In accordance with § 721.160(c)(3)(ii) and § 721.170(d)(4)(i)(B), the effective date of this rule is *[insert date 60 days after date of publication in the*

Federal Register] without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before *[insert date 30 days after date of publication in the Federal Register]*.

If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before *[insert date 30 days after date of publication in the Federal Register]*, EPA will withdraw the relevant sections of this direct final rule before its effective date. EPA will then issue a proposed SNUR for the chemical substance(s) on which adverse or critical comments were received, providing a 30-day period for public comment.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse or critical comments, or notice of intent to submit adverse or critical comments, must identify the chemical substance and the new use to which it applies. EPA will not withdraw a SNUR for a chemical substance not identified in the comment.

VII. Applicability of Rule to Uses Occurring Before Effective Date of the Rule

Significant new use designations for a chemical substance are legally established as of the date of publication of this direct final rule, *[insert date of publication in the Federal Register]*.

To establish a significant “new” use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no other person may commence such activities without first submitting a PMN. For chemical substances for which an NOC has not been submitted at this time, EPA concludes that the uses are not

ongoing. However, EPA recognizes that prior to the effective date of the rule, when chemical substances identified in this SNUR are added to the TSCA Inventory, other persons may engage in a significant new use as defined in this rule before the effective date of the rule. However, 6 of the 9 chemical substances contained in this rule have CBI chemical identities, and since EPA has received a limited number of post-PMN *bona fide* submissions (per §§ 720.25 and 721.11), the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

As discussed in the April 24, 1990 SNUR, EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of this direct final rule rather than as of the effective date of the rule. If uses begun after publication were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notification requirements because a person could defeat the SNUR by initiating the significant new use before the rule became effective, and then argue that the use was ongoing before the effective date of the rule. Thus, persons who begin commercial manufacture, import, or processing of the chemical substances regulated through this SNUR will have to cease any such activity before the effective date of this rule. To resume their activities, these persons would have to comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions expires.

EPA has promulgated provisions to allow persons to comply with this SNUR before the effective date. If a person meets the conditions of advance compliance under § 721.45(h), the person is considered exempt from the requirements of the SNUR.

VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. The two exceptions are:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists recommended testing for non-5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.”

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. Procedural Determinations

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at 40 CFR 721.1725(b)(1).

Under these procedures a manufacturer, importer, or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer, importer, or processor must show that it has a *bona fide* intent to manufacture, import, or process the chemical substance and must identify the specific use for which it intends to manufacture, import, or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture, import, or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI,

manufacturers, importers, and processors can combine the *bona fide* submission under the procedure in § 721.1725(b)(1) with that under § 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, i.e., the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture, import, or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

X. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§ 721.25 and 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substances subject to

this rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2012-0842.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

This rule establishes SNURs for several new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause"

under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RAF)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this rule.

This rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit XI. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

- Submission of the SNUN would not cost any small entity significantly more than \$8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this rule. As such, EPA has determined that this rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and

responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This rule does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This rule does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

XIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 13, 2012.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

.

Therefore, 40 CFR parts 9 and 721 are amended as follows:

PART 9--[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In § 9.1, add the following sections in numerical order under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
Significant New Uses of Chemical Substances	
* * * * *	
721.10629	2070-0012
721.10630	2070-0012
721.10631	2070-0012
721.10632	2070-0012
721.10633	2070-0012
721.10634	2070-0012

721.10635	2070-0012
721.10636	2070-0012
*	*

* * * *

PART 721--[AMENDED]

3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

4. Add § 721.10629 to subpart E to read as follows:

§ 721.10629 Fatty acids, tall-oil, reaction products with modified fatty acids and polyalkanolamines (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fatty acids, tall-oil, reaction products with modified fatty acids and polyalkanolamines (PMN P-09-107) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=110).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

5. Add § 721.10630 to subpart E to read as follows:

§ 721.10630 Amino acid, carboxyalkyl, alkylsulfonate, alkali salt (generic).

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified generically as amino acid, carboxyalkyl, alkylsulfonate, alkali salts (PMNs P-11-619 and P-11-620) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (where N = 770 parts per billion (ppb) for the aggregate of the PMN substances, P-11-619 and P-11-620). When calculating the surface water concentrations according to the instructions in § 721.90 (a)(4), (b)(4), and (c)(4), the statement that the amount of the substances that will be released will be calculated before the substances enter control technology does not apply. Instead, if the waste stream containing the substances will be treated before release, then the amount of the substances reasonably likely to be removed from the waste stream by such treatment may be subtracted in calculating the number of kilograms released. No more than 90 percent removal efficiency may be attributed to such treatment.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

6. Add § 721.10631 to subpart E to read as follows:

§ 721.10631 Mixed metal borate (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as mixed metal borate (PMN P-12-64) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80 (s), (y)(1), and (y)(2).

(ii) [Reserved]

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section*. The provisions of § 721.1725(b)(1) apply to this section.

7. Add § 721.10632 to subpart E to read as follows:

§ 721.10632 Benzamide, N-[(cyclohexylamino)thioxomethyl]-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as benzamide, N-[(cyclohexylamino)thioxomethyl]- (PMN P-12-181; CAS No. 4921-92-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(ii) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N= 2).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

8. Add § 721.10633 to subpart E to read as follows:

§ 721.10633 Aromatic sulfonic acid amino azo dye salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as aromatic sulfonic acid amino azo dye salts (PMN P-12-276) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4) (National Institute for Occupational Safety and Health (NIOSH)-certified M100 respirator with an assigned protection factor of at least 10), (a)(6), (b) (concentration set at 0.1 percent), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(s) (10,000 kilograms).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

9. Add § 721.10634 to subpart E to read as follows:

§ 721.10634 Iodonium, diphenyl-, 4,4'-di-C10-13-alkyl derivs., (OC-6-11)-hexafluoroantimonates(1-).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as iodonium, diphenyl-, 4,4'-di-C10-13-alkyl derivs., (OC-6-11)-hexafluoroantimonates(1-) (PMN P-12-464; CAS No. 1370442-66-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (photoinitiator used for ultraviolet release coatings).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

10. Add § 721.10635 to subpart E to read as follows:

§ 721.10635 Alkyl maleimide substituted bicyclic olefin (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkyl maleimide substituted bicyclic olefin (PMN P-12-480) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

11. Add § 721.10636 to subpart E to read as follows:

§ 721.10636 Slimes and sludges, automotive coating, wastewater treatment, solid waste.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as slimes and sludges, automotive coating, wastewater treatment, solid waste (PMN P-12-501; CAS No. 1392095-50-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (v)(1), (w)(1), and (x)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[FR Doc. 2012-30695 Filed 12/19/2012 at 8:45 am; Publication Date: 12/20/2012]